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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/554,410	11/17/2005	Giovanni Paganelli	GRT/4865-17	4581

23117 7590 07/31/2008
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EXAMINER	
GUSSOW, ANNE	
ART UNIT	PAPER NUMBER
1643	
MAIL DATE	DELIVERY MODE
07/31/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/554,410	PAGANELLI ET AL.	
	Examiner	Art Unit	
	ANNE M. GUSSOW	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-14 and 18-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-13 and 18-28* is/are rejected.

7)☒ Claim(s) *14* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/28/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1 and 18 have been amended.

Claims 2 and 17 have been canceled.

Claims 23-28 have been added.

2. Claims 1, 3-14, and 18-28 are under examination.

Priority

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. Applicant has submitted a certified translation of the Italian foreign priority document. Accordingly the claims receive support from this document and receive the priority date of April 24, 2003 for art rejection purposes.

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on May 28, 2008 was filed after the mailing date of the first action on the merits on November 26, 2007. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner and an initialed copy of the IDS is included with the mailing of this office action.

Rejections Withdrawn

5. The rejection of claims 1 and 3-14 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in view of applicant's arguments.

6. The rejection of claims 1, 3-8, 10-13, 18, 20-22 under 35 U.S.C. 102(b) as being anticipated by Goldenberg is withdrawn in view of applicant's arguments.

7. The rejection of claims 1, 3-8, 10-14, 18, and 20-22 under 35 U.S.C. 103(a) as being obvious over Goldenberg, et al. in view of Stendel, et al. is withdrawn in view of applicant's filing of the translation of the foreign priority document.

Claim Objections

8. Claim 14 is objected to as being dependent upon a rejected base claim.

Rejections Maintained

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The rejection of claims 1, 3-13, 18-22 and newly added claims 23-28 under 35 U.S.C. 103(a) as being obvious over Goldenberg in view of Cokgor, et al. is maintained.

The response filed April 28, 2008 has been carefully considered but is deemed not to be persuasive. The response states that Goldenberg administers the labeled antibody parenterally to the patient. Cokgor discloses that an anticancer agent, which is linked to a labeled antibody, is injected locally into of a surgically created resection cavities (SCRC). In Cokgor, the labeled antibody and the anticancer agent are administered together and at the same moment, i.e. during the intraoperative step (i.e., resection) and locoregionally (i.e., into the SCRC). By contrast, in the claims of the present application, the method comprises the following: (a) an agent endowed with tumor tropism, which binds to a molecule specifically produced by the tumour, is administered locoregionally during the surgery then, (b) an anticancer agent is administered parenterally after the surgery. Here, the effectiveness of this method of treatment is achieved by the first agent being endowed with the ability to concentrate the anticancer agent at the tumor site. The characterizing feature of the claimed invention is that the first agent endowed with tumor tropism and the anticancer agent are administered separately and at two different stages. Thus, this method allows the administration of the anticancer agent after surgery and ensures that it moves specifically toward the area where the agent endowed with tumor tropism was located during the surgery (see response pages 8-9).

In response to this argument, Cokgor, et al. teach administration of the antibody locally, directly into the surgical resection cavity which would be considered both

intraoperatively (within surgery) and locoregionally (locally). Cokgor, et al. teach a number of reasons for administering the antibody in this manner as opposed to surgically as set forth in the previous office action. These reasons include the small amount of monoclonal antibody that will cross the blood brain barrier, high interstitial fluid pressure in tumors and surrounding normal tissue, lack of monoclonal antibody specificity and less than optimal binding affinity (see Cokgor page 3862). Goldenberg teaches administration of two compositions at two different stages. First administration of a composition comprising avidin or streptavidin and second a composition comprising biotin. Goldenberg teaches a purpose of this administration is to provide method for close-range intraoperative, laparoscopic, intravascular, or endoscopic detection and treatment of non-malignant pathological lesions (paragraph 23). Goldenberg teaches administration of both compositions parenterally, however, since Cokgor, et al. teach reasons for local administration, one of ordinary skill in the art would be motivated to and have a reasonable expectation of success to administer the first composition of Goldenberg locally and the second composition at a later time as taught by Goldenberg parenterally.

Therefore, after a fresh consideration of the claims and the evidence provided, the rejection is maintained.

Conclusion

11. No claims are allowed.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNE M. GUSSOW whose telephone number is (571)272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow

July 25, 2008

/David J Blanchard/
Primary Examiner, Art Unit 1643